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December 10, 2019

*Via ECF Filing*

The Honorable P. Kevin Castel  
United States District Court for the Southern District of New York  
Daniel Patrick Moynihan Courthouse  
500 Pearl Street  
New York, NY 10007

**Re: Novartis Pharma AG v. Amgen Inc., 19-cv-2993 (PKC)**

Dear Judge Castel:

I write to request a pre-motion discovery conference to address Novartis's disclosure to us yesterday—the deadline for producing documents (see Order Extending Discovery Deadlines, ECF No. 51)—that it has withheld certain documents in its possession relating to Alder. *See Ex. A, Email from P. Gordon to E. Eun (Dec. 9, 2019).* Amgen responded to Novartis's disclosure yesterday, contesting the basis for Novartis's failure to complete its document production by the court-ordered deadline, and requesting confirmation that the Alder-related documents would be produced immediately. *See Ex. B, Email from E. Eun to P. Gordon (Dec. 9, 2019).* This evening, Novartis notified Amgen that it has “sent a small subset of documents to Alder for review in advance of production” but did not indicate when it will produce those documents to Amgen. *Ex. C, Email from S. Skarlatos to X. Wang (Dec. 10, 2019).* Amgen therefore seeks the Court's intervention in light of the fact that the deadline for producing documents has already passed. The next conference is scheduled for April 13, 2020 at 2:00 p.m.

As the Court is aware, the central issues in this case relate to Novartis's breach of its Agreements with Amgen; one of Novartis's Affiliates has been manufacturing a competing product for Alder BioPharmaceuticals. Since June 28, 2019, Amgen has requested from Novartis various categories of documents that “relate” to Alder. *See Ex. D, Amgen's First Request for Production of Documents to Novartis (June 28, 2019), Nos. 3–4, 6–11, 14–23; Ex. E, Amgen's Third Request for Production of Documents to Novartis (Sept. 24, 2019), Nos. 53–57, 59–60; Ex. F, Amgen's Fourth Request for Production of Documents to Novartis (Oct. 10, 2019), Nos. 63–65.* Fact discovery was originally supposed to be completed by December 13, 2019. Civil Case Management Plan & Scheduling Order, ECF No. 27 ¶ 5. At Novartis's request, the Court extended the discovery schedule, but ordered that Novartis produce documents by December 9, 2019—a date that Novartis itself selected. ECF No. 51.

*The application  
is denied as most  
in view of the  
representations  
in the letter  
of December 13,  
2019 (Dox 63).  
SO ORDERED  
S. J. M. 12-19-19  
VSD*

December 10, 2019

*Novartis Pharma AG v. Amgen Inc.*, 19-cv-2993 (PKC)

Yesterday—the day the Court ordered that document production be completed—counsel for Novartis for the first time notified Amgen that, “[t]o the extent that [Novartis] ha[s] confidential documents relating to Alder,” it planned to “provide the documents to Alder’s counsel to review in advance of production and, if Alder so requires [Novartis] will mark the documents ‘Highly Confidential - Outside Counsel Only’” before producing such documents to Amgen. Ex. A. Novartis stated that it is merely following the “same protocol as the one that [Amgen] agreed to with Sandoz GmbH . . . .” *Id.* But there is no such protocol. Nor is there any valid justification for Novartis’s late proposal and refusal to produce the documents to Amgen directly and immediately.

Novartis has not identified any basis even to suggest that with respect to Alder-related documents it has been relieved of the Court-ordered document production deadline of December 9, 2019. The fact that it did not merely underscores that Novartis has not taken to heart the Court’s prior admonition that the parties work diligently to complete discovery in a timely manner. *See* ECF No. 51. Novartis cannot unilaterally decide, on the date of the Court-ordered deadline for document production, that it will withhold an untold number of responsive, non-privileged documents in its possession for an undefined period of time, particularly given the fact that depositions must be completed by March 27, 2020, and depositions of Novartis current and former employees have already been noticed for next month. *Id.*

Even putting aside the December 9 deadline, Amgen has not agreed to any such protocol with Sandoz—or for that matter with Alder—as Novartis asserts. On July 3, 2019, Amgen served a subpoena on Alder—a non-party—for documents related to this litigation, including the Alder-Sandoz Contract Manufacturing Agreement and all related attachments, schedules, and amendments (“CMA”). Ex. G, Alder Subpoena (July 2, 2019), Request No. 1. To expedite non-party *Alder’s* production of a fully unredacted version of the CMA, amendments, and schedules *only*, Amgen agreed it would not share those fully unredacted documents with anyone other than outside counsel, experts, court reporters, or the author(s) or recipient(s) of the documents. *See* Ex. H, Letter from C. Durbin to B. Bishop & J. Fuisz (Sept. 25, 2019). All other confidential documents produced by Alder in response to the subpoena have and will be designated in accordance with the agreed Protective Order.<sup>1</sup> Consistent with its agreement with Alder, Amgen agreed that in providing information directly to Amgen Sandoz could also designate the same unredacted CMA and related amendments and agreements “Highly Confidential – Outside Counsel Only,” but that the Protective Order’s provisions would otherwise apply. *See* Ex. I, Email from R. Polechronis to B. Bank, J. Fuisz, D. Hille & B. Bishop (Nov. 1, 2019). But Amgen never agreed that Sandoz should send Alder-related documents to Alder’s counsel to review for confidentiality prior to production to Amgen.

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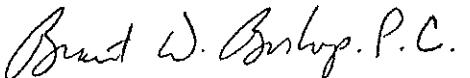
<sup>1</sup> Amgen and Novartis did, however, agree that with respect to any produced documents designated as Highly Confidential by Alder, such documents would only be shared with certain designated in-house litigation counsel, rather than the up to eight Designated House Counsel permitted to view Highly Confidential documents pursuant to the agreed Protective Order. *See* ECF No. 30 ¶ 6.3(b).

December 10, 2019  
*Novartis Pharma AG v. Amgen Inc.*, 19-cv-2993 (PKC)

The accommodation that Amgen gave to a third party, Alder, to expedite its subpoena response does not relieve Novartis of its obligations as a named party to produce information directly to Amgen. Nor are confidentiality concerns over Novartis's own documents a justifiable excuse to ignore the Court-ordered deadline and further delay document production. After all, Novartis itself agreed to the Stipulated Protective Order that has been in place since June 17, 2019. *See generally* ECF No. 30. This Order already provides measures for "special protection from public disclosure" of the parties' "confidential, proprietary, or private information." *Id.* at 1. There is simply no reason to delay production of confidential documents in Novartis's possession to Amgen.

Amgen therefore respectfully requests that the Court hold a pre-motion discovery conference to address Novartis's failure to produce responsive, non-privileged documents by the Court-ordered document production deadline. Amgen certifies that it in good faith attempted to confer with Novartis in an effort to obtain Alder-related documents from Novartis without Court action. Should this issue not be resolved at conference, Amgen will move to compel Novartis to produce the Alder-related documents. *See* Local Civ. R. 37.2.<sup>2</sup>

Respectfully submitted,



Brant W. Bishop, P.C.

cc: Counsel of Record (*Via ECF Filing*)

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<sup>2</sup> Amgen expects that it may have to raise additional issues related to Novartis's production with the Court in the near future. As Novartis has acknowledged, it continues to produce documents past yesterday's Court-ordered deadline, and has not notified Amgen when it expects to fully complete its production of documents. *See* Ex. C (stating that even with an anticipated production tonight and another tomorrow, its production of all documents will only be "substantially complete").